

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

EXPRESS MAIL NO. ED941899407US
DOCKET NO. PC25819A

Applicant's or agent's file reference 25819/700163	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/IB2005/000733	International filing date (day/month/year) 21.03.2005	Priority date (day/month/year) 26.03.2004
International Patent Classification (IPC) or national classification and IPC A61K31/345, A61K31/22, A61P3/06		
Applicant WARNER-LAMBERT COMPANY LLC et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 17.05.2005	Date of completion of this report 23.02.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Venturini, F Telephone No. +49 89 2399- 	

INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITYInternational application No.
PCT/IB2005/000733**10/594348****Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*.

Description, Pages

1-26 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Sheets

1/20-20/20 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2005/000733

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-7,9,13-15
	No: Claims	8,10-12
Inventive step (IS)	Yes: Claims	1-7,9,14-15
	No: Claims	8,10-13
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

SECTION V

1. Reference is made to the following documents:

D1: US-B1-6 190 894

D2: WO 02/48325

D1 deals with compositions comprising fluvastatin and β -chloroalanine which are HMG CoA reductase inhibitor and SPT inhibitor, respectively.

D2 deals with the preparation of a medicament for modulating SPT for the treatment of, inter alia, diabetes.

In view of the available prior art the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 8,10-12 is not new in the sense of Article 33(2) PCT.

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 8,10-13 does not involve an inventive step in the sense of Article 33(3) PCT. The problem to be solved by the present application may be formulated as how to provide a pharmaceutical composition comprising a SPT inhibitor and a second compound. The solution proposed is to provide a second compound which is useful in the treatment of atherosclerosis or dyslipidemia. However said solution has been already provided by D1 and cannot therefore be considered as inventive.